K062323

NOV - 1 2006

510(k) SUMMARY

Deltec Cozmo™ Insulin Infusion Pump

I. GENERAL INFORMATION

Applicant's Name and Address:	Smiths Medical MD, Inc. 1265 Grey Fox Road St. Paul, MN 55112
Contact Person:	David H. Short Director Regulatory and Clinical Affairs
Common/Usual Name:	Insulin Infusion Pump and Glucose Monitor
Proprietary Name:	Deltec Cozmo® Insulin Infusion Pump Model 1800 with CoZmonitor® Blood Glucose Module
Equivalence Device Comparison:	Deltec Cozmo® Insulin Infusion Pump and Animas IR 1250

II. DEVICE DESCRIPTION

The Deltec Cozmo® Insulin Infusion Pump with CoZmonitor® Blood Glucose Module is lightweight and easy to use. The Deltec Cozmo® Insulin Pump incorporates a number of features to assist users in the management of their diabetes. Some of these features include a quick start program to allow users easy pump set-up and programming, enhancements to existing features, the addition of a food data base, user established blood glucose targets and alerts, insulin-on-board to alert the user of remaining active insulin following bolus administration, pump disconnect feature that allows the user to disconnect from the pump and allowing the pump to then keep track of insulin that would have been delivered during the disconnect period, Hypo Manager that alerts the patient of low BG levels and recommends carbohydrate units to ingest to elevate BG to patient specific specified levels, Therapy Summary Report to assist with diabetes management, weekly schedule to allow the user to set basal patterns to match activities of daily living. The Deltec Cozmo® Insulin Pump is used with the CoZmonitor® Blood Glucose Module

The CoZmanager® 2.0 is a PC based program that allows the user to download information from the pump and to program the pump via an IR connection between the pump and the PC. CoZmanager® 2.0 allows the user to customize names of features as well as establish meal selections based on individual needs. A number of reports are available from the program.

III. INTENDED USE OF THE DEVICE

The Deltec Cozmo® Insulin Pump is a syringe infusion pump designed for Continuous Subcutaneous Insulin Infusion (CSII) for the control of diabetes.

IV. DEVICE COMPARISON

The Deltec Cozmo® Insulin Pump Model 1800 is similar to the currently distributed Deltec Cozmo® Insulin Pump Model 1700 pump, with the exception of updated software that enhanced certain features and added a food data base to allow users to better manage dietary requirements in conjunction with the use of their insulin pump.

The Deltec Cozmo® Insulin Pump Model 1800 is substantially equivalent to other commercially available insulin pumps such as the Animas IR 1250.

V. SUMMARY OF STUDIES

A. Functional Testing

Verification and validation of software controlled programming functions related to proper pump operation were conducted and results of this testing showed the Deltec Cozmo® Insulin Pump Model 1800 met and performed to established specifications.

B. Clinical Studies

Clinical studies were not deemed necessary to establish effectiveness of the Deltec Cozmo® Insulin Pump Model 1800 as the pump is similar to other currently commercially available insulin pumps on the market today.

C. Conclusion Drawn from the Studies

Based on the information provided above, the Deltec Cozmo® Insulin Pump Model 1800 is substantially equivalent to other currently commercially available insulin infusion pumps on the market today.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 1 2006

Mr. David H. Short
Director Regulatory Affairs and Design Assurance
Smiths Medical MD, Incorporated
1265 Grey Fox Road
St. Paul, Minnesota 55112

Re: K062323
Trade/Device Name: Deltec Cozmo® Insulin Pump with CoZmonitor™ Glucose Monitor
Regulation Number: 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: LZG
Dated: October 9, 2006
Received: October 10, 2006

Dear Mr. Short:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062323

Device Name: Deltec Cozmo® Insulin Pump with CoZmonitor™ Glucose Monitor

Indications for Use:

Deltec Cozmo® Insulin Pump

The Deltec Cozmo® Insulin Pump is a syringe infusion pump designed for Continuous Subcutaneous Insulin Infusion (CSII) for the control of diabetes.

Prescription Use ___X___ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

Indications for Use:

CoZmonitor™ Glucose Monitor

The Deltec CoZmonitor™ Blood Glucose Monitor is available as an accessory to be used solely with the Deltec Cozmo® Insulin Pump. Because the monitor is powered by FreeStyle™, blood sampling can be performed using the finger, forearm, upper arm, thigh, calf or hand. All testing is performed outside of the body (in other words, *in-vitro* diagnostic use only). Use only with FreeStyle™ Test Strip and FreeStyle™ Control Solution, as other products can give inaccurate results.

Prescription Use _____ OR Over-The Counter Use ___X___
(Per 21 CFR 801.109)

Indications for Use:

Deltec Cozmo® Insulin Pump with CoZmonitor™ Glucose Monitor

The Deltec CoZmonitor™ Blood Glucose Monitoring System is designed to be used only with the Deltec Cozmo® Insulin Pump to help you and your healthcare provider monitor your diabetes management program. When used properly, the monitor provides a quantitative measurement of glucose (or sugar) in whole blood. Because the monitor is powered by FreeStyle™, blood sampling can be performed using the finger, forearm, upper arm, thigh, calf or hand. All testing is performed outside of the body (in other words, *in-vitro* diagnostic use only). Use only with FreeStyle™ Test Strip and FreeStyle™ Control Solution, as other products can give inaccurate results.

Prescription Use ___X___ OR Over-The Counter Use _____
(Per 21 CFR 801.109)

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[illegible]
[illegible]ology, General Hospital
[illegible], Dental Devices

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